

Notice of Allowability**Application No.**

10/766,074

Applicant(s)

DONOHO ET AL.

Examiner

Art Unit

Yong D Pak

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to the preliminary amendment filed on January 28, 2004.

2. The allowed claim(s) is/are 6.

3. The drawings filed on are accepted by the Examiner.

4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of the:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. .

3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received:

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) hereto or 2) to Paper No./Mail Date .

(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
Paper No./Mail Date .

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1/28/2004
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other

DETAILED ACTION

This application is a divisional of 10/214,811, now issued as U.S. Patent No. 6,743,621, which is a continuation of 09/780,016, now issued as U.S. Patent No. 6,509,456.

The preliminary amendment filed on January 28, 2004, canceling claims 1-2 and adding claims 6-7, has been entered.

Claims 2-7 are pending. Claims 3-5 and 7 are withdrawn. Claim 6 is under consideration.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 3, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO:20, classified in class 536, subclass 23.2.
- II. Claim 4, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO:24, classified in class 536, subclass 23.2.
- III. Claim 5, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO:26, classified in class 536, subclass 23.2.
- IV. Claim 6, drawn to a polypeptide of SEQ ID NO:2, classified in class 435, subclass 212.
- V. Claim 7, drawn to an antibody against the polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.9.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are patentably distinct products.

The polynucleotide of groups I-III and the polypeptide of groups IV-V are patentably distinct inventions for the following reasons. Polypeptides, are composed of amino acids and polynucleotides are composed of purine and pyrimidine units. Also the polynucleotides of groups I-III do not encode the polypeptides of groups IV-V.

Furthermore, searching the inventions of groups I-V together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I-V have a separate status in the art as shown by their different classifications.

The polypeptide of group IV and the antibody of group V are patentably distinct for the following reasons:

While the inventions of both group IV and group V are polypeptides, in this instance the polypeptide of group IV is a single chain molecule that functions as an enzyme, whereas the polypeptide of group V encompasses antibodies. Thus the polypeptide of group IV and the antibody of group V are structurally distinct molecules; any relationship between a polypeptide of group IV and an antibody of group V is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group IV is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group V is defined in terms of its binding specificity to a small structure within SEQ ID

NO: 2. Thus immunization with the polypeptides of group IV would result in the production of antibodies outside the scope of group V.

Furthermore, searching the inventions of group IV and group V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group V. Furthermore, antibodies which bind to an epitope of a polypeptide of group IV may be known even if a polypeptide of group IV is novel. In addition, the technical literature search for the polypeptide of group IV and the antibody of group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Groups I-III and V, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Mr. Hibler on November 29, 2004 a provisional election was made without traverse to prosecute the invention of Group IV, claim 6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-5 and 7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Hibler on December 6, 2004.

The application has been amended as follows:

IN THE CLAIMS:

Cancel claims 3-5 and 7.

Allowable Subject Matter

Claim 6 is allowed.

The following is an examiner's statement of reasons for allowance:

Prior art revealed no suggestion of a protease having the amino acid sequence of SEQ ID NO:2. Therefore, the protease of SEQ ID NO:2 is novel and non-obvious over the prior art.

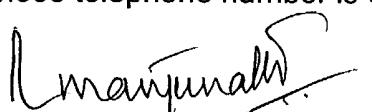
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652


Rao Manjunath
Primary Examiner 1652
Art Unit 1652